



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

Information Program on Clinical Trials: Maintaining a Registry and Results Databank
(NLM)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on June 10, 2015, page 32968 and allowed 60-days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Library of Medicine (NLM), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: David Sharlip, Office of Administrative and Management Analysis Services,, National Library of Medicine, Building 38A, Room B2N12, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll-free number (301) 402-9680, or E-mail your request, including your address to: sharlipd@mail.nih.gov Formal requests for additional plans and instruments must be requested in writing.

PROPOSED COLLECTION: Information Program on Clinical Trials: Maintaining a Registry and Results Databank (NLM), 0925-0586, Expiration Date 08/31/2015, EXTENSION, National Library of Medicine (NLM), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Institutes of Health operates ClinicalTrials.gov, which was established as a clinical trial registry under section

113 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) and was expanded to include a results data bank by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA). ClinicalTrials.gov collects registration and results information for clinical trials and other types of clinical studies (e.g., observational studies and patient registries) with the objectives of enhancing patient enrollment and providing a mechanism for tracking subsequent progress of clinical studies, to the benefit of public health. It is widely used by patients, physicians, and medical researchers; in particular those involved in clinical research. While many clinical studies are registered and submit results information voluntarily, FDAAA requires the registration of certain applicable clinical trials of drugs and devices and the submission of results information for completed applicable clinical trials of drugs and devices that are approved, licensed, or cleared by the Food and Drug Administration. Beginning in 2009, results information was required to include information about serious and frequent adverse events.

This extension request does not include any changes to the information submission requirements for ClinicalTrials.gov that were proposed in the Notice of Proposed Rulemaking on Clinical Trial Registration and Results Submission that was issued on November 21, 2014 and for which the public comment period closed on March 23, 2015 (79 FR 225, Nov. 21, 2014). The NIH is continuing to review submitted public comments as it prepares the final rule. The NIH will make any corresponding changes to the ClinicalTrials.gov information collection via separate procedure.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 682,535.

Estimated Annualized Burden Hours

Submission Type	Number of Respondents	Number of Response per Respondent	Average Time per Response (In hours)	Total Annual Hour Burden
PRS Account	5,700	1	15/60	1,425
Initial Registration	23,000	1	7	161,000
Updates	23,000	8	2	368,000
Initial Results	3,700	1	25	92,500
Updates	3,700	2	8	59,200
Certification to Delay Results	700	1	30/60	350
Extension Request	30	1	2	60

Dated: August 13, 2015

David Sharlip

Project Clearance Liaison

NLM, NIH

[FR Doc. 2015-20473 Filed: 8/18/2015 08:45 am; Publication Date: 8/19/2015]